

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1517 w/CS On-line Pharmacy/Controlled Substances

SPONSOR(S): Homan and others

TIED BILLS: None.

IDEN./SIM. BILLS: CS/SB 2310 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Health Standards (Sub)</u>	<u>7 Y, 0 N</u>	<u>Mitchell</u>	<u>Collins</u>
2) <u>Health Care</u>	<u>19 Y, 0 N w/CS</u>	<u>Mitchell</u>	<u>Collins</u>
3) _____	_____	_____	_____
4) _____	_____	_____	_____
5) _____	_____	_____	_____

SUMMARY ANALYSIS

HB 1517 addresses the problem of medicinal drugs, including controlled substances, being provided to the public through internet pharmacies without being prescribed by a physician or the patient consulting a physician in person. It establishes grounds for discipline of pharmacists who fill such prescriptions, requires internet pharmacies selling drugs in Florida to be licensed, and provides penalties for unlicensed pharmacies.

Internet pharmacies sell pharmaceutical products to consumers through their websites. The number of prescription drug websites has grown dramatically in recent years. "Internet pharmacies" fall into three types (Rost, Kerry "Policing the 'Wild West' World of Internet Pharmacies," 76 Chicago-Kent Law Review 1333, 2000):

- Pharmacies that only dispense prescriptions that are written by a patient's physician;
- Pharmacies that have the patient complete a cyber consultation for a fee and then write a prescription for the patient; and
- Pharmacies that dispense prescription drugs without a physician's prescription.

The bill:

- Amends s. 465.016, F.S., to include as grounds for disciplinary actions against a pharmacist, the dispensing of a prescribed drug when the pharmacist knows or should know that the prescription is not based on a valid relationship between the patient and the prescriber;
- Amends s. 465.003, F.S., to include a definition of "internet pharmacy" and require that such pharmacies selling drugs in Florida be licensed under ch. 465, F.S.;
- Creates s. 465.0161, F.S., to provide that an internet pharmacy that distributes drugs to people in Florida without being licensed as a pharmacy is guilty of a second degree felony; and
- Amends s. 895.02, F.S., to add the criminal offense for distributing drugs as an unlicensed internet pharmacy provided in s. 465.0161, F.S., to the definition of racketeering activity and prosecution.

The bill provides an effective date of upon becoming law.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h1517b.hc.doc

DATE: April 16, 2003

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|------------------------------|--|---|
| 1. Reduce government? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. Empower families? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a "no" above, please explain:

The bill creates requires internet pharmacies to be licensed in Florida and provides for criminal penalties and prosecution.

B. EFFECT OF PROPOSED CHANGES:

HB 1517 addresses the problem of medicinal drugs, including controlled substances, being provided to the public through internet pharmacies without being prescribed by a physician or the patient consulting a physician in person. It establishes grounds for discipline of pharmacists who fill such prescriptions, requires internet pharmacies selling drugs in Florida to be licensed, and provides penalties for unlicensed pharmacies.

The bill:

- Amends s. 465.016, F.S., to include as grounds for disciplinary actions against a pharmacist, the dispensing of a prescribed drug when the pharmacist knows or should know that the prescription is not based on a valid relationship between the patient and the prescriber;
- Amends s. 465.003, F.S., to include a definition of "internet pharmacy" and require that such pharmacies selling drugs in Florida be licensed under ch. 465, F.S.;
- Creates s. 465.0161, F.S., to provide that an internet pharmacy that distributes drugs to people in Florida without being licensed as a pharmacy is guilty of a second degree felony; and
- Amends s. 895.02, F.S., to add the criminal offense for distributing drugs as an unlicensed internet pharmacy provided in s. 465.0161, F.S., to the definition of racketeering activity and prosecution.

The bill provides an effective date of upon becoming law.

PRESENT SITUATION:

Regulations regarding the licensure of pharmacies are currently under the jurisdiction of the Board of Pharmacy and the Division of Medical Quality Assurance of the Department of Health. Pharmacies are licensed under the provisions of chapter 465, F.S., the Pharmacy Practice Act. Sections 465.0156, 465.018, and 465.022, F.S., require the licensure of all pharmacies providing prescription drug services to patients in Florida, including those pharmacies with an Internet presence.

Internet Pharmacies:

Internet pharmacies sell pharmaceutical products to consumers through their websites. The number of prescription drug websites has grown dramatically in recent years. "Internet pharmacies" fall into three types (Rost, Kerry "Policing the 'Wild West' World of Internet Pharmacies," 76 Chicago-Kent Law Review 1333, 2000):

- Pharmacies that only dispense prescriptions that are written by a patient's physician;

- Pharmacies that have the patient complete a cyber consultation for a fee and then write a prescription for the patient; and
- Pharmacies that dispense prescription drugs without a physician's prescription.

The National Association of Boards of Pharmacies (NABP) considers the use of on-line consultation without a valid physician-patient relationship to be illegal. NABP believes that no additional laws are needed to regulate internet pharmacies. The NABP focuses on the need for existing state regulators to police internet pharmacies. To support this effort, the NABP established the Verified Internet Pharmacy Practice Sites program, as a voluntary, private certification program for internet pharmacies to help the public identify internet pharmacies that are properly licensed. To join the program, a pharmacy must comply with licensing and inspection requirements of their state and of each state to which they dispense drugs. If there is a conflict between any state laws, the pharmacy agrees to comply with the more stringent law.

The Federal Trade Commission (FTC) has jurisdiction to take action against claims that constitute health fraud on the internet. The FTC may take action against the owners of a website for false or misleading claims regarding the safety or effectiveness of any pharmaceuticals offered, but does not make any effort to police the practice of medicine or pharmacy.

Pharmacy Regulation:

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy regulates the practice of pharmacy in Florida. Every pharmacy must be permitted and each pharmacy is subject to discipline for violations of applicable state or federal law relating to pharmacy. Pharmacies are subject to inspection by the Department of Health.

Any pharmacy that is located outside of Florida and that ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state is considered a nonresident pharmacy, and must register with the Florida Board of Pharmacy and make specified disclosures to the board pursuant to s. 465.0156, F.S. Such disclosures include: the location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to Florida residents.

Section 465.015(3)(b), F.S., makes it unlawful for any person other than an owner of a registered pharmacy to display any sign or take any other action that would lead the public to believe that such person is engaged in the business of compounding, dispensing, or retailing, any medicinal drugs. The violation of s. 465.015(3)(b), F.S., constitutes a first degree misdemeanor punishable by imprisonment for up to 1 year or a fine of up to \$1,000.

The bill provides for a criminal penalty for an unlicensed internet pharmacy of a second degree felony, which is punishable by up to 15 years of imprisonment as provided in s. 775.082, F.S., and a fine of up to \$10,000, as provided by s. 775.083, F.S.

The Racketeer Influenced and Corrupt Organization (RICO) Act

The Florida Racketeer Influenced and Corrupt Organization Act (RICO) established in ch. 895, F.S., provides for both criminal and civil proceedings against organized criminal activity to enable prosecution of those involved in organizing the activity. The Office of the Attorney General and the State Attorney are responsible for enforcement of the RICO Act for enterprises involved in continuing patterns of illegal activities that are enumerated in s. 895.02(1)(a), F.S., including fraud, theft and misleading advertising.

Under provisions of the federal Racketeer Influenced and Corrupt Organization Act (RICO), upon which the Florida statute it modeled, the government may show that the racketeering acts found to have been committed pose a threat of continued racketeering activity by proving: (1) that the acts are part of a long-term association that exists for criminal purposes, or (2) that they are a regular way of conducting

the defendant's ongoing legitimate business, or (3) that they are a regular way of conducting or participating in an ongoing and legitimate enterprise. 18 U.S.C.A. § 1962(c) (West 1984).

C. SECTION DIRECTORY:

Section 1. Amends s. 465.016, F.S., relating to grounds for disciplinary action against pharmacists, to include dispensing of a prescribed drug when the pharmacist knows or should know that the prescription is not based on a valid relationship with a prescribing practitioner.

Section 2. Amends s. 465.003, F.S., to include a definition of "internet pharmacy" and require that such pharmacies selling drugs in Florida be licensed under ch. 465, F.S.

Section 3. Creates s. 465.0161, F.S., to provide that an internet pharmacy that distributes drugs in Florida without being licensed as a pharmacy, is guilty of a second degree felony.

Section 4. Amends s. 895.02, F.S., to add the criminal offense for distributing drugs as an unlicensed internet pharmacy to the definition of racketeering activity and prosecution.

Section 5. Establishes the effective date of the bill is upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Internet pharmacies will incur additional costs to become licensed in Florida.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

To the extent the bill requires "internet pharmacies" to become licensed in Florida the bill raises issues for the internet retailing activities under the Commerce Clause of the United States Constitution. The Commerce clause states that "Congress shall have Power... To regulate Commerce... among the several States...." U.S. Constitution article I, Section 8, cl. 3. Courts have used a two-tiered analysis to determine whether a statutory scheme violates the dormant Commerce clause: (1) If the scheme directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, it is generally struck down unless it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives; and (2) if the statute has only indirect effects on interstate commerce and regulates evenhandedly, whether, the burden on interstate commerce clearly exceeds the local benefits. See Bainbridge v. Turner, 311 F.3d 1104 (2002).

B. RULE-MAKING AUTHORITY:

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the department, it may not be possible to fully enforce the permitting provision or the pharmacy practice provisions of the bill since an on-line pharmacy may be operating outside jurisdictions of the state or the United States.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 2, 2003, the Health Standards Subcommittee adopted a "strike-all" amendment and reported the bill favorably to the Health Care Committee.

Amendment 1:

- Puts provisions for the bill in current s. 465.061, F.S., relating to disciplinary actions for pharmacists, instead of creating a new section 465.0158, F.S., relating to violations.
- Provides for disciplinary action against pharmacists for filling prescriptions that are written without a valid professional relationship with the prescribing health care practitioner.
- Amends s. 465.003 to provide a definition for "internet pharmacy."
- Creates s. 656.0161, F.S., which provides a penalty of a second degree felony for an internet pharmacy that distributes drugs to persons in Florida with being licensed in Florida.

On April 9, 2003, the Health Care Committee adopted an amendment to the "strike-all" amendment and reported the bill favorably. This analysis is drafted to the bill as amended.